Citation:

Haas CN, Marie JR, Rose JB, Gerba CP. Assessment of benefits from use of anti-microbial hand products: Reduction in risk from handling ground beef. *Int J Hyg Environ Health.* 2005; 208 (6): 461-466. Epub 2005

PubMed ID: 16325555

Study Design:

Meta-Analysis, Quantitative Microbial Risk Assessment

Class:

M - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To estimate the benefits resulting from the use of hand cleansing products (e.g., soaps) containing anti-microbial ingredients using Quantitative Microbial Risk Assessment (QMRA).

Inclusion Criteria:

To perform the risk assessment, data on a number of variables was required. These data were obtained from the literature:

- Density of pathogens in ground beef
- Transference of bacteria from beef to hands
- Removal or reduction of bacteria by hand washing products (without or containing antimicrobial agents)
- Transference of bacteria from hands to mouth
- Infectivity of ingested pathogens.

For removal or inactivation assessment, only studies that used the glove juice methodology (i.e.,human tests) as opposed to in vitro testing and having sufficient data to quantify the reduction ratio (N/N_0) were considered.

Exclusion Criteria:

- References that generated data from hospital or clinical studies, were excluded
- Much of the information in the literature was not usable due to lack of results to quantify N/N_0 (e.g., only ‘‘non-detects’’) and incomplete description of the methodology used for the study.

Description of Study Protocol:

Recruitment

An extensive literature search was completed in order to obtain the necessary data to perform the risk assessment.

- The first source of data included references currently in the files of the investigators that are available in the open literature
- The second source was from an extensive computer bibliographic search. Databases such as Index Medicus, Biological Abstracts, SCISEARCH and Web of Science were used to acquire relevant information from studies.

Design

Meta-analysis, Quantitative Microbial Risk Assessment (QMRA)

Blinding used

Not applicable

Intervention

Not applicable

Statistical Analysis

- Monte Carlo analysis (simulation)
- Statistical distributions were fitted to the data using Crystal Balls (R).
- The Kolmogorov-Smirnov test was used to determine which distribution best described the data.

Data Collection Summary:

Timing of Measurements

Data were obtained from the literature, and after screening for data quality, incorporated into a database and used to develop probability distributions.

Dependent Variables

- Infectivity dose response curve of non-O157:H7 pathogenic *E. coli* removal from hands by products with various active ingredients: Modeled by Monte Carlo analysis (simulation) using following data obtained from the literature:
    - Density of pathogens in ground beef
    - Transference of bacteria from beef to hands
    - Removal or reduction of bacteria by hand washing products (without or containing anti-microbial agents)
    - Transference of bacteria from hands to mouth
    - Infectivity of ingested pathogens.

Independent Variables

- Active ingredients analyzed in the model:
    - Alcohol

- Chlorhexidine/hibiclens (CHEX)
- Triclosan/hexachlorophene (TSAN)
- Iodine/povidone (Iodine)
- Parachlorometaxylenol (PCMX)
- Non-germicidal (NONG).

Description of Actual Data Sample:

- ***Initial N:***
  - Number of citations: Not described
  - Number of full-text screened and excluded articles: Not described
  - Number of articles included:
    - Alcohol: Two articles with 13 data points
    - Chlorhexidine/hibiclens (CHEX): Four articles with six data points
    - Triclosan/hexachlorophene (TSAN): Three articles with five data points
    - Iodine/povidone (Iodine): Three articles with six data points
    - Parachlorometaxylenol (PCMX): One articles with one data points
    - Non-germicidal (NONG): Two articles with four data points. (These studies had data on the removal of E. coli from hands using products at concentrations that could be found in consumer products).
- ***Attrition (final N):*** As above
- ***Age:*** Not applicable
- ***Ethnicity:*** Not applicable
- ***Other relevant demographics:*** None listed
- ***Anthropometrics:*** None listed
- ***Location:*** International studies.

Summary of Results:

Key Findings

- There is a reduction in risk from the use of any hand washing protocol as compared to no hand washing
- The amount of risk reduction obtained from the use of triclosan-containing products (as compared to handwashing using non-germicidal containing products) is smaller than that when products with alcohol or chlorhexidine as active ingredients are used
- Alcohol-based but not triclosan-based hand sanitizers are more effective than sanitizers not containing anti-microbials at reducing risk of transmission of *E. coli* pathogenic strains from ground beef to mouth.

Other Findings

- Percentile plot of *E. coli* removal by products containing different active ingredients (Qualitative analysis):
  - There is a difference in the degree of reduction exhibited by products with different active ingredients
  - This was confirmed by analysis of variance and in particular, the difference in reduction achieved by alcohol-containing products was significantly different from the other products (including no active ingredient)
  - Lodine-containing products were not considered further since they are not currently,

nor are they expected to be used in the consumer market

- Monte Carlo (simulation) results for lognormal probability plot for the *E. coli* case study:
  - Assumptions used in the simulation model: Assuming that there are 100 million individuals (in the US) each of whom handles ground beef once per month; this results in $1.2x10^9$ contacts per year. Assume 10% of these individuals contact hands to mouth after handling ground beef; $1.2x10^8$ incidents per year.
  - For *E. coli* O157:H7, using the median risk, this would result in an estimate ranging from 0.00005 (if all individuals used alcohol containing products between contact with ground beef and transference to the mouth) to 0.7 (if no hand washing is done) infections per year
  - It should also be noted that these risks are conditional in the sense that they quantify the risk to an individual who has handled ground beef and who engages in hand to mouth activity (with the stipulated hand cleansing behavior)
  - The probability that an individual who handles ground beef will engage in such behavior is not known, and therefore a direct comparison to actual disease rates cannot be made. However, with some plausible assumptions we may compare the outputs of this assessment to reported illness rates.
  - Simulation results showed that there is a higher probability of infection in the no hand-washing scenario when compared to the antibacterial hand washing scenario.

Author Conclusion:

This work has demonstrated that a Quantitative Microbial Risk Assessment (QMRA) framework can be applied to the estimation of benefits from use of anti-microbial hand products.

This was done by developing a model for the scenario of hand contact with ground beef during food preparation, considering transference of bacteria to the hands, removal and inactivation by handwashing and subsequent transference from the hands to the mouth.

Organisms of interest in this case study were pathogenic Escherichia coli and the particular strain *E. coli* O157:H7. It was found that QMRA could be applied to this problem and that the anti-microbials provided some quantifiable benefit (i.e., reduced the risk of infection and illness). Benefits from the use of triclosan-containing products were less than from the use of products in which alcohols or chlorhexidine were active ingredients.

Reviewer Comments:

There is currently no consensus on how to appraise the methodologic quality of risk assessment analysis. The quality assessment of this study was done using the quality appraisal tool for systematic review or meta-analysis. Thus the methodologic quality rating of this study may not represent the "true" quality of this study.

Based on reviewer's limited knowledge on simulation studies, this article appears to have good reporting on all the parameters in the analyses and provide good explanation for how the model was chosen and how to interpret the results. The assumptions and limitations on the simulation model were also provided.

Research Design and Implementation Criteria Checklist: Review Articles

Relevance Questions		
1.	Will the answer if true, have a direct bearing on the health of patients?	Yes
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes
3.	Is the problem addressed in the review one that is relevant to nutrition or dietetics practice?	Yes
4.	Will the information, if true, require a change in practice?	Yes

Validity Questions		
1.	Was the question for the review clearly focused and appropriate?	Yes
2.	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search termsused described?	???
3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	???
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	???
5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes
6.	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes
7.	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes
8.	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes
9.	Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes
10.	Was bias due to the review's funding or sponsorship unlikely?	Yes